

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 10/03/2011

FORM APPROVED

OMB NO. 0938-0391

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001069 | | (X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____ | | (X3) DATE SURVEY COMPLETED 08/09/2011 | |
| NAME OF PROVIDER OR SUPPLIER SURGICARE LLC | | | | STREET ADDRESS, CITY, STATE, ZIP CODE 2907 MCINTIRE DR STE C BLOOMINGTON, IN47403 | | | |
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| O0000 | <p>This visit was for a Federal recertification survey.</p> <p>Facility #: 009971</p> <p>Survey Dates: 08-08/09-11</p> <p>Surveyors: Billie Jo Fritch, RN, BSN, MBA Public Health Nurse Surveyor</p> <p>Jennifer Hembree, RN Public Health Nurse Surveyor</p> <p>QA: cloughlin 08/24/11</p> | | | O0000 | | | |

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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| O0082 | <p>(b)(1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.</p> <p>(b)(2) The ASC must use the data collected to -</p> <p>(i) Monitor the effectiveness and safety of its services, and quality of its care.</p> <p>(ii) Identify opportunities that could lead to improvements and changes in its patient care.</p> <p>(c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.</p> <p>(c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.</p> <p>Based on document review and interview, the facility failed to include discharges and nursing services in the facility Quality Assurance and Performance Improvement (QAPI) program to ensure the quality of services rendered.</p> <p>Findings include:</p> <p>1. Review of QAPI documents on 8-8-11 and 8-9-11 lacked evidence that discharges and nursing services were included in the facility QAPI program.</p> <p>2. Interview with #S1 on 8-9-11 at 1435 hours confirmed discharges and nursing services are not included in the facility's</p> | | | O0082 | <p>416.43 (b)(c) (2)(c) (3)(1)</p> <p>(2)Discharge and Nursing QA is monitored through the Post Op letters and the Medical Records Audit.When the information is gathered from the Post Op letters and the Medical Record Audit, comments are evaluated for possible improvement measures. Follow up calls or Re-education measures are made as needed for concerns.How to prevent reoccurrence: added to the agenda for Department meeting 8/17/11 This is also discussed at quarterly QA meetings.Responsibility: Executive Director</p> | | 08/17/2011 |

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| O0101 | <p>QAPI program to insure the quality of services provided.</p> <p>The ASC must provide a functional and sanitary environment for the provision of surgical services. Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area. Based on document review and interview, the facility created a condition which could compromise the safety of patients in the OR during a power failure requiring the use of the generator.</p> <p>Findings include:</p> <p>1. Review of facility documents on 8-8-11 and 8-9-11 indicated the following: September 10, 2011 The generator was run under load for 30 minutes. The line power light switched to the generator power light at the master panel when the generator was activated. The generator has been automatically running every Tuesday for 30 minutes (4:00 to 4:30 pm) as it has been pre-programmed. No problems found. Verified: RN #1 October 8, 2011 The generator was run under load for 30 minutes. The line power light switched to the generator</p> | | O0101 | <p>416.44 (a)(1)-(1) (2)The generator schedule with the expected outcomes is present in the log book. The log was revised to complete our Plan of Correction for the ISDH Survey conducted on April 28, 2011. This revision was accepted on June 17, 2011. The new log was placed in service in May, 2011. The previous log covers the prior months of 2011. The current log has been included. Prevention of reoccurrence: Executive director will review the log monthly for compliance and adherence to standards for testing. Responsibility: Executive Director</p> | | 08/17/2011 | |

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| | <p>power light at the master panel when the generator was activated. The generator has been automatically running every Tuesday for 30 minutes (4:00 to 4:30 pm) as it has been pre-programmed. No problems found. Verified: RN #1 November 5, 2011 The generator was run under load for 30 minutes. The line power light switched to the generator power light at the master panel when the generator was activated. The generator has been automatically running every Tuesday for 30 minutes (4:00 to 4:30 pm) as it has been pre-programmed. No problems found. Verified: RN #1 December 3, 2011 The generator was run under load for 30 minutes. The line power light switched to the generator power light at the master panel when the generator was activated. The generator has been automatically running every Tuesday for 30 minutes (4:00 to 4:30 pm) as it has been pre-programmed. No problems found. Verified: RN #1 Because these dates indicating the testing was done and verified have not yet occurred, it could not be determined that regular testing was being completed and documentation was accurate.</p> <p>2. Interview with #S1 on 8-9-11 at 0950 hours indicated the documents are a schedule.</p> | | | | | | |

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| O0103 | <p>[The ASC must provide a functional and sanitary environment for the provision of surgical services.]</p> <p>The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities. Based on staff interview and document review, the facility failed to ensure the ASC received infection surveillance information from all surgeons performing procedures at the facility.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Staff member #1 indicated in interview at 2:00 p.m. on 8/9/11 that post operative infections were tracked by receiving a log from each physician indicating whether the patient had a post operative infection. He/she indicated the surveillance was complete for the month of May. 2. Surveillance logs completed by the surgeons for the month of May did not include M.D. #10. 3. Review of the surgery log for May 2011 indicated that M.D. #10 performed 13 procedures on 5/5/11. | | | Q0103 | <p>416.44 (a)(3)- (1-3)The infection Control log from said physician was present at the time of the survey. It was overlooked and the vacation time was misquoted. the Log has been redesigned for easier access. The log was redesigned 8/9/2011.prevention of reoccurrence: Executive Director will review logs monthly to ensure that all physicians are listed and have reported post op infections to the center. Reviewed at the quarterly QA meetings.Responsibility: Executive Director</p> | | 08/09/2011 |

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| O0105 | <p>Emergency equipment available to the operating rooms must include at least the following:</p> <ul style="list-style-type: none"> (1) Emergency call system. (2) Oxygen. (3) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator. (4) Cardiac defibrillator. (5) Cardiac monitoring equipment. (6) Tracheostomy set. (7) Laryngoscopes and endotracheal tubes. (8) Suction equipment. (9) Emergency medical equipment and supplies specified by the medical staff. <p>Based on observation and interview, the facility failed to assure unexpired emergency supplies were available to the operating room.</p> <p>Findings:</p> <ul style="list-style-type: none"> 1. Review of the anesthesia cart contents beginning at 11:30 a.m. on 8/9/11 indicated the following expired items were in the cart: <ul style="list-style-type: none"> (A) Five (5) 18 GA 1.16 in IV catheters with an expiration date of 3/09. (B) Two (2) 24 GA .75 in. IV catheters with an expiration date of 4/10. 2. Review of the contents of the crash cart beginning at 1:20 p.m. on 8/9/11 indicated the following expired items were in the cart: <ul style="list-style-type: none"> (A) Eight 10 cc syringes with expiration | | | O0105 | <p>All outdated supplies were discarded and replaced. Entire staff re-educated during the department meeting on 8/17/2011. prevention of reoccurrence: Executive Director will review the crash cart log and check for outdated supplies every month and document findings. Director will document on "Monthly Drug Storage" checklist and redport to the QA committee. Responsibility: Executive Director</p> | | 08/17/2011 |

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| O0181 | <p>dates ranging from 2/2003-0/2004.</p> <p>(B) Two (2) 3 cc Syringes with expiration dates of 10/2003.</p> <p>(C) Four (4) Cuffed 3.5 tracheal tube with an expiration date of 1/2011.</p> <p>(D) One (1) uncuffed 3.0 tracheal tube with an expiration date of 9/2008.</p> <p>(E) One (1) uncuffed 4.0 tracheal tube with an expiration date of 12/2008.</p> <p>3. Staff member #1 verified expired items at 5:05 p.m. on 8/9/11.</p> <p>Drugs must be prepared and administered according to established policies and acceptable standards of practice. Based on observation, document review and interview, the facility failed to label pre-filled syringes with date, time, initials, content and expiration date and failed to discard single dose vials after use.</p> <p>Findings include:</p> <p>1. During tour of the pre/post operative area beginning at 10:35 a.m. on 8/9/11, one (1) 50 ml vial of Sodium Bicarbonate was observed in a medication cabinet. The opened vial was marked as "single dose" and dated as opened on 7/1/11.</p> <p>2. During observation of the contents of the anesthesia cart in OR #2 beginning at 11:30 a.m. on 8/9/11, the following was</p> | | | O0181 | <p>416.48 (a)(1)(2) Medication in the single dose vial was discarded and replaced. Education on proper labelling and discarding of single dose vials was completed in the department meeting on 8/17/11. Re-education conducted with anesthesiologist on the same date. prevention of recurrence: The Executive director will monitor proper labelling and discarding of single dose vials every month for six months. The director will document on the "Monthly Drug Storage" checklist and report to the QA committee. Responsibility: Executive Director</p> | | 08/17/2011 |

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| | <p>observed:</p> <p>(A) One (1) 20 ml unlabeled pre-drawn syringe containing a milky white solution was observed in the second drawer.</p> <p>3. Facility policy titled "MEDICATIONS-ADMINISTERING, STORAGE, AND ORDERING/RECEIVING" last reviewed/revised 7/20/09 states on page 4 of 7: "9. All medications, medication containers (i.e., syringes, medicine cups, basins) or other solutions on and off the sterile field in peri-operative and other procedural settings will be labeled."</p> <p>4. Anesthesia provider #1 indicated in interview at 11:35 a.m. on 8/9/11 that the unlabeled syringe with milky white solution was drawn up "for the next patient."</p> | | | | | | |

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| O0225 | <p>(i) The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC.</p> <p>(v) The grievance process must specify timeframes for review of the grievance and the provisions of a response.</p> <p>(vi) The ASC, in responding to the grievance, must investigate all grievances made by a patient or the patient's representative regarding treatment or care that is (or fails to be) furnished.</p> <p>(vii) The ASC must document how the grievance was addressed, as well as provide the patient with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed.</p> <p>Based on document review and interview, the facility failed to specify timeframes for review of grievances and timeframes for the response to the patient or the patient's representative.</p> <p>Findings include:</p> <p>1. Review of facility policy titled Customer Grievance Policy on 8-9-11 indicated the following on page 2, #9: "The patient or representative will be contacted and results of the investigation will be communicated". The policy lacked documentation to specify timeframes for the review or the requirement for a written response to the</p> | | | O0225 | <p>The Grievance policy has been update to include the time frame for review and the written response. Policy attached. Responsibility: Executive Director</p> | | 08/15/2011 |

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| O0230 | <p>patient or the patient's representative regarding the results of the grievance process.</p> <p>2. Interview with #S1 on 8-9-11 at 1400 hours confirmed the facility policy titled Customer Grievance Policy lacks documentation to specify timeframes for the review or a written response with the results of the grievance process to the patient or the patient's representative.</p> <p>(2) If a patient is adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf.</p> <p>(3) If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.</p> <p>Based on document review and interview, the facility failed to develop a policy/procedure to address the rights of a patient if they have been adjudged incompetent under applicable state health and safety laws by a court of proper jurisdiction.</p> <p>Findings include:</p> <p>1. Review of policies and procedures on 8-8-11 and 8-9-11 lacked evidence of a facility policy to address the rights of a patient if they have been adjudged</p> | | | O0230 | <p>416.50 (b)(2) 416.50(b)(3)</p> <p>(1)The patient rights have been revised. Revised patient rights document attached. the areas of revision are highlighted. revision 9/8/11. staff education to take place on 9/13/11prevention of reoccurrence: Patient Rights will be changed or revised according to regulatory requirements and changes will only be made by the Executive Director.Responsibility: Executive Director</p> | | 09/08/2011 |

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| O0241 | <p>incompetent under applicable state health and safety laws by a court of proper jurisdiction.</p> <p>2. Interview with #S1 on 8-9-11 at 1235 hours confirmed the facility does not have a policy to address the rights of a patient if they have been adjudged incompetent under applicable state health and safety laws by a court of proper jurisdiction.</p> <p>The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.</p> <p>Based on observation, interview, and document review, the facility failed to ensure the provision of a sanitary environment and failed to appropriately dispose of biohazardous waste.</p> <p>Findings include:</p> <p>1. During tour of the operative area beginning at 11:25 on 8/9/11, the following was observed: (A) Fluid waste from procedure performed on patient #N30 containing 5000 ml sterile water with blood and urine in it was observed double bagged in regular trash bags and put in with regular trash.</p> <p>2. During observation of terminal</p> | | | O0241 | <p>416.51 (a) (1-11)Re-education on proper handling and discarding of BioHazard material / waste was completed on 8/10/2011. The policy and use of the drain in the OR Urology room was initiated. Education on terminal cleaning was performed on 8/23/2011. Education included:1) The change into scrubs will be performed in the changing room.2) the floor will be cleaned daily with a disinfected and weekly cleaner followed by disinfectant. 3)Instruction on cleaning from clean to dirty4)Instruction on proper measuring and mixing of products.The Director will monitor proper disposal of biohazard waste and document on the Infection Control Worksheet and report to the Infection Control committee which is reviewed by</p> | | 08/23/2011 |

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| | <p>cleaning of the OR's beginning at 4:35 p.m. on 8/8/11 the following was observed:</p> <p>(A) Staff members #E1 and E2 failed to change into scrub attire in the staff dressing room. They did not enter the dressing room area prior to arriving to lounge area and wearing their scrub attire.</p> <p>(B) The scrub attire for the cleaning staff was located in the boiler room. All other scrub attire was located in the staff dressing rooms.</p> <p>(C) Review of the label for Enzibrite cleaner indicated the cleaner was a bacterial enriched floor cleaner, odor eliminator, and grease digester and was not a disinfectant. The label states "For use on floor only." Label mixing instructions indicated for light duty cleaning -2 ounces of the product was to be used per gallon of water.</p> <p>(D) Staff member #E2 was observed starting in the doorway of OR #2 and working his/her way around the room clock wise. He/she worked from soiled areas such as the sharps container, cart casters and baseboards to cleaner areas such as tables and the anesthesia machine.</p> <p>(E) Enzibrite enzyme enriched floor cleaner & deodorizer was used for all surfaces in the OR with exception of the floor. The solution was mixed by staff member #E2 using "1 squirt of cleaner and 1/2 bucket of water." The size of the</p> | | | | the QA committee.Resposibility: Exectutive Director | | |

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| | bucket was unknown by the staff member. 3. RN #1 indicated in interview at 12:15 p.m. on 8/9/11 that the facility used to bag waste from procedures in biohazard bags, however it became too expensive to do so. 4. RN #2 indicated the following in interview at 2:40 p.m. on 8/9/11: (A) Irrigation fluids containing blood and urine are double bagged after a procedure and put in the trash receptacle in the soiled utility room. (B) The facility does not flush the contaminated irrigation solution down the hopper. 5. Staff member #E2 indicated during observation beginning at 4:35 p.m. on 8/8/11 that he/she puts 1 squirt of the Enzibrite cleaner in 1/2 bucket of water. He/she did not know the size of the bucket used. 6. Facility policy titled "RECOMMENDED (known error in spelling) CLEANING PROCEDURES" last reviewed/revised 7/20/09 states on page 7: "B. Agents labeled as hospital disinfectants that are germicidal/virucidal/tuberculocidal are acceptable cleaning agents....." | | | | | | |

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| | <p>7. Facility policy titled "HOUSEKEEPING INFECTION CONTROL" last reviewed/revised 7/20/09 states on page 7: "C. Cleaning with an approved germicidal/viracidal/tuberculocidal product shall be a regular part of the daily housekeeping routine, as a means of suppressing infectious matter carried by drafts, on shoes, and any other means throughout the Center. Germicidal products shall have the ability to both clean and disinfect....."</p> <p>8. Facility policy titled "TERMINAL CLEANING OF THE OPERATING ROOM SUITE" last reviewed/revised 7/20/09 states on page 11 under equipment: "C. Approved disinfectant." and under procedure: "3. Wash the room and equipment from cleanest to dirtiest. (Those things above the floor are assumed to be less dirty than those closer to, or on the floor."</p> <p>9. Facility policy titled "HOUSEKEEPING SERVICES" last reviewed/revised 7/20/09 states on page 4: "F. Location of cleaning apparel/changing areas. 1. Scrub suites and related garb should be obtained and put on using the staff dressing rooms."</p> <p>10. Facility policy titled "METHODS OF</p> | | | | | | |

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| | <p>COMPLIANCE TO BLOOD PATHOGEN STANDARD" last reviewed/revised 7/20/09 states on page 19: "i. Contaminated work surfaces are to be decontaminated with an appropriate disinfectant after the completion of procedures, immediately or as soon as achievable after overt contamination or any spoil of blood or PIM, and at the end of the workshift if the surface may have been contaminated since the last cleaning....."</p> <p>11. Facility policy titled "INFECTIOUS WASTE POLICY" last reviewed/revised 7/20/09 states on page 2: " II DEFINITION: A. Infectious waste, in this policy, is defined as waste that epidemiologic evidence indicates is capable of transmitting a dangerous communicable disease. At the Center, this includes, but is not limited to: 1. All blood and blood products in liquid or semi-liquid form.....5. All materials and disposables that have come in contact with infectious waste.....IV. PROCEDURES: A. All employees will dispose of items exposed to body fluids, tissue, and/or blood in the properly designated receptacles that are identified by a biohazard symbol." and page 3 of the policy states "F. If infectious waste is to be stored prior to final disposal: 1. Store in a secure area that: a. Is locked or</p> | | | | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 10/03/2011

FORM APPROVED

OMB NO. 0938-0391

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| | otherwise secured to avoid access by or exposure to the general public. b. Gives protection from adverse environmental conditions and vermin. c. Has a prominently displaced biohazard symbol. 2. Store infectious waste so that the integrity of the container is maintained, and the environment is not conducive to rapid microbial growth and putrefaction." | | | | | | |